IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

WILLIAM L. BELL, JR,	)	CIVIL ACTION NO. 17-1153
	)	
Plaintiff,	)	
	)	
	)	
v.	)	
	)	
	)	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, AND; AND ELI LILLY & COMPANY,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

Conti, Chief District Judge

I. Introduction

Plaintiff William L. Bell, Jr. ("Bell") alleges that he developed an acute kidney injury as a direct result of taking the prescription drug Jardiance. The court dismissed the original complaint in its entirety based upon the lack of actual facts pled about how each defendant acted negligently or fraudulently in Jardiance's design or warnings or how each defendant's alleged breaches of the standard of care caused Bell's injuries. (February 15, 2018 Opinion, ECF No. 20). The court gave Bell leave to file an amended complaint, but cautioned him to plead how the design or warnings were faulty and to assure that the complaint contained sufficient factual allegations to render the claims "plausible" against each defendant, because the court was unlikely to permit further amendment. *Id*.

Bell filed an amended complaint. (ECF No. 22). Defendants Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI")[1] and Eli Lilly & Company ("Lilly") renewed their motions to dismiss the amended complaint in its entirety. (ECF Nos. 24, 26). Both defendants contend that Bell again failed to plead sufficient facts to support any cognizable claims. Lilly filed a separate motion, arguing that because BIPI is the sole applicant holder of the Jardiance New Drug Application ("NDA") filed with the Food and Drug Administration ("FDA") Lilly never had authority to change Jardiance's labeling or design. The motions are fully briefed and ripe for disposition.

II. Documents considered

A court may properly look at public records without converting a motion to dismiss into one for summary judgment. *Johnson v. Talton*, No. CV 17-01446, 2018 WL 1427086, at *1 (W.D. Pa. Mar. 22, 2018) (citing *Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999), and *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). A plaintiff with a legally deficient claim cannot survive a motion to dismiss simply by failing to attach a dispositive document on which he relied. *Pension Ben. Guar. Corp*., 998 F.2d at 1196.

The court will take judicial notice of the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The Orange Book is a "publically available list of drugs which have been approved [by the FDA] for safety and effectiveness." *Warren v. Boehringer Ingleheim Pharm. Inc*., No. 116CV01326SEBDML, 2017 WL 3970666, at *16 (S.D. Ind. Sept. 8, 2017) (citing *Abbott Labs. v. Zenith Labs., Inc*., 934 F. Supp. 925, 927 (N.D. Ill. 1995), and *Morris v. Wyeth, Inc*., No. 9-854, 2012 WL 601455 (W.D. La. Feb. 23,

[1] Two other Boehringer entities named as defendants have not yet been served.

2012)). The Orange Book lists BIPI as the sole "applicant holder" for Jardiance. *Id.*; *avail. at* www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=204629, last visited on May 22, 2018.

Numerous courts have concluded that FDA warning letters are publicly available evidence of agency actions, of which the court may take judicial notice. *Bowling v. Johnson & Johnson*, No. 17-CV-3982, 2018 WL 1587598, at *4 (S.D.N.Y. Mar. 28, 2018) (collecting decisions); *accord Allred v. Frito-Lay N. Am., Inc.*, No. 17-CV-1345, 2018 WL 1185227, at *2 (S.D. Cal. Mar. 7, 2018) ("FDA warning letters available on the FDA's website are also appropriate subjects of judicial notice") (citation omitted); Fed. R. Evid. 201. In *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 750-51 (W.D. Pa. 2011), the court took judicial notice of the medication's package warning label in granting a motion to dismiss design and failure to warn claims. The court will consider FDA warning letters and label changes regarding SGLT2 inhibitors such as Jardiance. *See, e.g., Bowling*, 2018 WL 1587598, at *4 (and decisions cited therein).

The court will consider the FDA's NDA Approval letter (ECF No. 25-1), which is referenced in the amended complaint (ECF No. 22 ¶¶ 21-22) and integrally related to the claims in this case. The court will consider the information available at the FDA website, www.accessdata.fda.gov, last visited on May 22, 2018, to which both parties have cited. (ECF No. 22 n. 3, 4; ECF No. 25 at 8 n.4). These documents will be considered for their existence, but not for the truth of the facts recited therein. *Southern Cross Overseas Agencies*, 181 F.3d at 426.

III. Factual Background

Despite the court's conclusion in the February 15, 2018 memorandum opinion that the

allegations in Bell's original complaint were conclusory and substantially identical to those held to be insufficient in several other cases, the amended complaint makes only a few factual revisions. (Compare ECF Nos. 1, 22). The court will incorporate its recitation of the factual background in the February 15, 2018 memorandum opinion and set forth the additional facts to be considered from the amended complaint and documents from the FDA website.

> As set forth in the complaint, in July 2014, defendants submitted an NDA to the FDA for Jardiance. Complaint ¶ 20 (ECF No. 1). In August 2014, the FDA approved Jardiance for the treatment of Type II diabetes. *Id.* ¶ 21. Jardiance is the tradename for the drug empagliflozin, which is a member of the gliflozin class of sodium-glucose cotransporter 2 ("SGLT2") inhibitors. *Id.* ¶ 22. SGLT2 inhibitors are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. *Id.* ¶ 24. Excess glucose is not metabolized. Instead, it is excreted through the kidneys. *Id.* ¶ 24. Jardiance is indicated for only improved glycemic control in type 2 adult diabetics, but defendants market it for off label purposes, including weight loss, reduced blood pressure and improved glycemic control in type 1 diabetes. *Id.* ¶ 25. Since the release of Jardiance, the FDA has received a significant number of reports of diabetic ketoacidosis. *Id.* ¶ 26. Bell alleges that defendants knew about the significant risk of diabetic ketoacidosis but did not adequately warn consumers or the medical community about the severity of such risks. *Id.* ¶ 30.
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> On June 13, 2015, Bell began taking Jardiance per his doctor's instructions, primarily to treat diabetes. *Id.* ¶ 32. Bell relied on defendants' claims that Jardiance was safe and effective for the treatment of diabetes. *Id.* ¶ 35. On August 31, 2015, Bell suffered acute renal failure. *Id.* ¶ 37.

(February 15, 2018 memorandum opinion, ECF No. 20).

In response to the court's comment that Bell did not plead the roles of each defendant, he now pleads that BIPI and Lilly agreed to jointly develop and commercialize diabetes compounds and "worked in conjunction to research, develop, test and market Jardiance." (ECF No. 22 ¶ 19). In response to the court's comment that Bell failed to identify alternative, safer designs, he now pleads that other products were available, including metformin, Diabinese, Amaryl and Glucotrol. (ECF No. 22 ¶ 41). The amended complaint does not contain any facts about why these products are safer or why the design of Jardiance was negligent.

Bell added some details about his own condition. He developed type-2 diabetes in 2005. (ECF No. 22 ¶ 34). He began taking 25 milligrams of Jardiance daily on June 13, 2015, as prescribed by his physicians at Joslin Diabetes Center. (ECF No. 22 ¶ 34). At the time he was prescribed Jardiance, he had normal kidney function. (ECF No. 22 ¶ 34). He suffered an acute kidney injury on August 31, 2015. (ECF No. 22 ¶ 38). Bell avers that despite his kidney injury, he continued taking Jardiance daily for five more months, through February 3, 2016. (ECF No. 22 ¶ 34).

Bell pleaded additional details about the FDA's approval and warnings about Jardiance and the risks of kidney damage. Bell recognized that the FDA approved Jardiance's NDA in August 2014 after some "previously observed deficiencies" led the FDA to stay its decision for several months. (ECF No. 22 ¶ 23). Bell does not describe these "deficiencies." Bell alleged that although defendants knew the risks for kidney damage in August 2014, the original label warnings and precautions failed to mention acute kidney injury or renal failure. (ECF No. 22 ¶ 24 & n.3) (citing www.accessdata.fda.gov/drugsatfda_docs/label/2014/204629s000lbl.pdf), last visited on May 22, 2018 ("Original Label"). The court takes judicial notice of the contents of that label. Bell pleaded that in June 2016, the FDA "replaced the current warnings about the risk of acute kidney injury" for other SGLT2 inhibitor medications, but did not provide similar warnings to Jardiance users until December 2016. (ECF No. 22 ¶ 28). Bell quoted the December 2016 FDA warning that Jardiance can cause renal impairment and there were postmarketing reports of acute kidney injury in patients receiving SGLT2 inhibitors, some involving patients younger than 65 years of age. (ECF No. 22 ¶ 40 & n.4) (citing https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf), last visited on May 22, 2018. Bell did not state his own age.

The FDA's approval of the Jardiance NDA required that the label (package insert and patient information) be identical to the approved text. (ECF No. 25-1). The FDA approval letter required a clinical trial, in part to address "signals of serious risks" of, among other conditions, acute kidney injury. *Id*. at 5.

The Original Label for Jardiance contained several references to kidney and renal functioning. The Dosage and Administration section stated: "Assess renal function before initiating JARDIANCE. Do not initiate JARDIANCE if eGFR is below 45 mL/min/1.73 m^2 (2.2)." Original Label at 1. One of two contraindications to taking JARDIANCE was "Severe renal impairment, end-stage renal disease, or dialysis (4)." *Id*. The Warnings and Precautions section provided: "*Impairment in renal function*: Monitor renal function during therapy. More frequent monitoring is recommended in patients with eGFR below 60 mL/min/1.73 m^2 (5.2)." *Id.* Section 2.2 (Patients with Renal Impairment) stated: "Assessment of renal function is recommended prior to initiation of Jardiance and periodically thereafter." *Id*. Sections 4, 5.2, 6, 8.5, 8.6 and 12.3 contained additional references to impairment in renal functioning. *Id*. In Section 14.3 and Table 10, the Original Label described a study involving the safety and efficacy of Jardiance in patients with mild, moderate or severe renal impairment. *Id.* at 21. The Patient Information stated that a patient should tell his doctor if he has kidney problems before taking Jardiance, and that "JARDIANCE may cause serious side effects, including . . . kidney problems, especially in people 75 years of age or older and people who already have kidney problems." *Id*. at 26-27.

Bell did not include any averments about publicly available information regarding kidney injuries associated with SGLT2 inhibitors on the FDA's Adverse Event Reporting System ("FAERS") prior to the time he began taking Jardiance. From March 29, 2013 to October 19,

2015, FAERS recorded 101 cases of acute kidney injury involving SGLT2 inhibitors. (June 14, 2016 FDA Warning, www.fda.gov/Drugs/DrugSafety/ucm506772.htm, last visited on April 27, 2018). Bell pleaded that on June 14, 2016, the FDA "strengthened the existing warning about the risk of acute kidney injury" for the SGLT2 medications canagliflozin and dapagliflozin. (*Id.*; ECF No. 22 ¶ 28). In December 2016, the FDA strengthened the label warning about acute kidney injury for Jardiance. (ECF No. 22 ¶ 28; https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf), last visited on May 22, 2018.

IV. Standard of Review

A motion to dismiss tests the legal sufficiency of the complaint. *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). In deciding a motion to dismiss, the court is not opining on whether the plaintiff will be likely to prevail on the merits; rather, when considering a motion to dismiss, the court accepts as true all well-pled factual allegations in the complaint and views them in a light most favorable to the plaintiff. *U.S. Express Lines Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002). While a complaint does not need detailed factual allegations to survive a Federal Rule of Civil Procedure 12(b)(6) ("Rule 12(b)(6)") motion to dismiss, a complaint must provide more than labels and conclusions. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A "formulaic recitation of the elements of a cause of action will not do." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "Factual allegations must be enough to raise a right to relief above the speculative level" and "sufficient to state a claim for relief that is plausible on its face." *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the

misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

> The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully.. . . Where a complaint pleads facts that are"merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

Id. (quoting *Twombly*, 550 U.S. at 556) (internal citations omitted).

Two working principles underlie *Twombly*. *Id*. First, with respect to mere conclusory statements, a court need not accept as true all of the allegations contained in a complaint. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555.) Second, to survive a motion to dismiss, a claim must state a plausible claim for relief. *Id.* at 679. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* (citing 490 F.3d at 157-58). "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not 'show[n]- that the pleader is entitled to relief."' *Id.* (quoting Fed. R. Civ. P. 8(a)(2)). A court considering a motion to dismiss may begin by identifying pleadings that are not entitled to the assumption of truth because they are mere conclusions.

> While legal conclusions can provide the framework of the complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Id.

V. Legal Analysis

The amended complaint asserts the following causes of action: (1) negligence; (2) fraudulent misrepresentation; (3) negligent misrepresentation; (4) negligent design; (5) fraudulent concealment; and (6) fraud. Defendants seek dismissal of all claims with prejudice.

1. Omnibus negligence claim

The amended complaint contains a boilerplate laundry-list of alleged negligence that is virtually identical to the negligence claim in the original complaint. (*Compare* ECF No. 1 ¶¶ 102-118 *with* ECF No. 22 ¶¶ 52-68). The numerous defects identified by the court in dismissing the original negligence claim apply equally to the amended complaint. The allegations continue to constitute conclusory repackaging of the elements of the claim without supporting facts to render the claim plausible. *See House v. Bristol-Myers Squibb Co.*, No. 3:15-894, 2017 WL 55876 (W.D. Ky. Jan. 4, 2017); *Fleming v. Janssen Pharmaceuticals, Inc.*, 186 F. Supp. 3d 826, 835 (W.D. Tenn. 2016). The amended complaint does not provide any facts about how defendants breached their duty or how defendants' conduct caused Bell's injury.

Bell did not directly respond to defendants' motion to dismiss the negligence claim in count 1, although he did argue generally that his claims were neither preempted nor insufficiently pled. His primary negligence theory appears to be that defendants had a duty to initially design Jardiance differently to mitigate the risks of severe kidney injury prior to its approval by the FDA. (ECF No. 29 at 6).[2] He conclusorily argues that defendants should have changed the label to warn about kidney injury after FDA approval.[3] (ECF No. 29 at 7). Bell did not plead how the original warnings about Jardiance fell below the required standard of care, what new information defendants obtained or when they obtained it, what the strengthened

[2] This argument will be addressed *supra* because Bell pleaded a separate "negligent design" claim.
[3] Defendants briefed why the "changes being effected" ("CBE") regulation did not apply, but Bell did not respond to this argument.

warning should have said, or how defendants' alleged breaches of duty caused his injury. The negligence claim will be dismissed.

2. Negligent misrepresentation claim

In the February 15, 2018 memorandum opinion, the court held that a claim for negligent misrepresentation in the prescription drug context is not barred by *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), but dismissed Bell's claim for failure to plead sufficient facts. The negligent misrepresentation claim in the amended complaint is entirely duplicative of the allegations in the original complaint. (*Compare* ECF No. 1 ¶¶ 158-173 *with* ECF No. 22 ¶¶ 76-91). Bell again pleaded only conclusory restatements of the elements of the claim with no specific underlying facts. Bell did not directly respond to defendants' renewed motion to dismiss the negligent misrepresentation claim. For the reasons set forth above and in the February 15, 2018 memorandum opinion, this claim will be dismissed.

3. Negligent design claim

Bell opposes dismissal of the negligent design claim. He recognizes that under Pennsylvania law, he must plead that the manufacturer owed a duty, breached that duty, such breach was the proximate cause of his injuries, and "an alternative, safer design would have lessened or eliminated the injury plaintiff suffered." (ECF No. 29 at 7, citing *Salvio*, 810 F.Supp.2d at 752). Bell argues that this claim is sufficiently pled because he identified several safer alternative products, namely, metformin, Diabinese, Amaryl and Glucotrol. (ECF No. 22 ¶ 41).[4]

In a subsequent decision in *Salvio v. Amgen Inc.*, No. 2:11-CV-00553, 2012 WL 517446

[4] Bell's brief also criticized the FDA for not including Jardiance in its June 2016 warning that SGLT2 inhibitors canagliflozin and dapagliflozin posed risks of acute kidney injury. (ECF No. 22 ¶ 28, ECF No. 29 at 7). It is unclear how this argument advances a negligent design claim against defendants.

(W.D. Pa. Feb. 15, 2012), the court held that "an alternative design must not be an altogether essentially different product." *Id*. at *7 (collecting decisions for the proposition that a plaintiff "cannot point to an entirely different product as an alternative design"). As in *Salvio*, Bell failed to allege any alternative ways in which Jardiance could have been designed. Instead, he merely listed completely different drugs that he could have taken. Bell did not plead how the design of Jardiance is defective. In addition, Bell failed to allege any facts to show that a reasonable alternative design for Jardiance could have been practically adopted by defendants. *Id*. The negligent design claim will be dismissed.

4. Fraud claims

Bell contends that the fraudulent misrepresentation, fraudulent concealment and fraud claims in counts 2, 5 and 6 of his amended complaint are sufficiently pled. Bell's theory is that defendants made concerted (albeit unspecified) efforts to suppress and conceal critical information regarding the risks of Jardiance from the FDA, the public, Bell and Bell's physicians. (ECF No. 29 at 8). Bell cited no legal authority for his position.

In the February 15, 2018 memorandum opinion, the court concluded that Pennsylvania law recognizes a cause of action for fraudulent marketing of prescription drugs, but noted that such claims must meet rigorous pleading standards pursuant to Federal Rule of Civil Procedure 9(b). *See House*, 2017 WL 55876 at *8 (dismissing fraud-based claims described at a high level of generality).

There are no averments in the amended complaint about what information was suppressed or concealed. In the amended complaint, Bell recognized that prior to approving the NDA, the FDA observed deficiencies that led it to stay its decision for several months. (ECF No. 22 ¶ 23). The Jardiance Original Label advised that renal function should be assessed before

initiating Jardiance and periodically thereafter; identified contraindications for renal impairment; and warned of impairment in renal function. Bell also pleaded that the FDA received a significant number of reports of acute kidney injury among users of Jardiance after its release. (ECF No. 22 ¶ 30). The "who, what, when, where and how" of defendants' alleged fraud, i.e., the "first paragraph of any newspaper story," is missing. *See In re Rockefeller Center Properties Inc. Sec. Litig.*, 311 F.3d 198, 218 (3d Cir.2002). The fraud-based claims in the amended complaint again fall far short of the Rule 9 pleading standard and must be dismissed.

VI. Conclusion

In sum, the amended complaint fails to plead sufficient facts to make any claim "plausible," as required by the Federal Rules of Civil Procedure. The amended complaint, therefore, will be dismissed in its entirety. The court need not address Lilly's separate motion to dismiss.

VII. Leave to Amend

Bell again requested leave to amend the complaint in the event that the motions to dismiss were granted. Pursuant to Rule 15, leave to amend should be freely granted unless an amendment would be inequitable, or otherwise unjust by way of futility, bad faith, or undue delay. *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006). As explained above, Bell failed to correct the shortcomings identified by the court in the February 15, 2015 memorandum opinion.

The legal principles governing preemption of state law claims in the prescription drug area are complex. State law "fraud on the FDA" claims based upon alleged failures to provide

information to the FDA prior to a drug's initial approval are preempted because "the federal statutory scheme amply empowers the FDA to punish and deter fraud." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347 (2001). Failure to warn claims based upon alleged deficiencies in the initial label are preempted. *MacMurray v. Boehringer Ingelheim Pharm., Inc*., No. 17-195 (D. Utah, September 6, 2017) (ECF No. 25-2) (involving Jardiance); *McGee v. Boehringer Ingelheim Pharm., Inc.,* No. 16-2082, 2018 WL 1399237 (S.D. Ala., March 20, 2018) (ECF No. 25-3) (involving Jardiance). There is a narrow legal theory that may be cognizable, however, involving a duty to warn about Jardiance's risks *after* the FDA's initial approval but *before* Bell's injury. *McGee*, 2018 WL 1399237 at * 4. To successfully state a claim under this theory, Bell must allege that new information became available to defendants during this period which should have prompted them to change the Jardiance label under the CBE regulations. *Id*. at * 4-5.

It is not entirely certain that permitting another amendment would be unjust, futile or would cause undue delay. Leave to amend will be granted one more time. The first amended complaint will be dismissed without prejudice. If Bell again attempts to replead, it will be incumbent upon him to *clearly* articulate the legal theory he is pursuing and to allege sufficient facts to make each element of the claim plausible. He must also eliminate his overbroad, conclusory "shotgun" allegations so that defendants are given adequate notice of what Bell claims they did wrong. *Id*. at * 5.

In accordance with the foregoing, Defendants' joint motion to dismiss amended complaint (ECF No. 24) will be GRANTED, and Lilly's separate motion to dismiss (ECF No. 26) will be DENIED AS MOOT. An appropriate order will be entered.

May 31, 2018

/s/ Joy Flowers Conti
Joy Flowers Conti
Chief United States District Judge